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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/521,002	01/07/2005	Sean Mark Dalziel	CL2101USPCT	4855

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Legal Patents
Wilmington, DE 19898

EXAMINER	
VETERE, ROBERT A	
ART UNIT	PAPER NUMBER
1792	
MAIL DATE	DELIVERY MODE
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/521,002	DALZIEL ET AL.	
	Examiner	Art Unit	
	ROBERT VETERE	1792	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *07 January 2005*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-20* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-20* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *07 January 2005* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *7/05*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Claim Rejections - 35 USC § 103

1. Claims 1, 3-6, and 18 are rejected under 35 U.S.C. 103(a) as being unpatentable over Handjani et al. (US 6,203,802) in light of Fujiura et al. (US 5,002,986).

Claims 1 and 5-6: Handjani teaches a method of coating nanoparticles with a size of 10-1000nm (3:1-3) with polyunsaturated fatty acids (3:36-50) wherein the fatty acids on the loaded particles are 60 wt% or greater (3:55-58) to produce a particle useful in pharmaceutical treatment (Abst.). Handjani fails to teach the steps of claim 1, but teaches that the nanoparticles may be coated by any known process (4:32). Fujiura teaches a method of coating particles comprising high intensity mixing of liquids with fine particles in a fluid mixer by suspending the fine particles in a turbulent gas stream and contacting the particles with a liquid sprayed from a pressurized nozzle (6:54-66). Thus, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have coated the nanoparticles of Handjani using the method of Fujiura with the predictable expectation of success because Handjani explains that any known method may be used to coat the nanoparticles.

Claims 3-4: Handjani also teaches that the coating composition may be aqueous or non-aqueous (3:59-65).

2. Claim 8 is rejected under 35 U.S.C. 103(a) as being unpatentable over Handjani and Fujiura in light of Barnhart et al. (US 5,762,952).

Claim 8: Handjani and Fujiura fail to teach that the coating process is repeated. However, Barnhart teaches that it is known in the art to repeat coating processes on pharmaceutical devices in order to obtain a coating with a desired thickness (8:5-7). Thus, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have repeated the steps of claim 1 in order to have obtained a coating with a desired thickness.

3. Claims 1, 5-6, 14 and 18 are rejected under 35 U.S.C. 103(a) as being unpatentable over Zaffaroni (US 3,921,636) in light of Fujiura.

Claims 1, 14 and 18: Zaffaroni teaches a method of forming nanoparticles having a size of 5-7 nm (see, e.g., 12:61-62) useful as drug release devices (Abst.) which can be loaded using any known

technique (7:47-48). Fujiura teaches a method of coating particles comprising high intensity mixing of liquids with fine particles in a fluid mixer by suspending the fine particles in a turbulent gas stream and contacting the particles with a liquid sprayed from a pressurized nozzle (6:54-66). Thus, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have coated the nanoparticles of Zaffaroni using the method of Fujiura with the predictable expectation of success because Zaffaroni explains that any known method may be used to coat the nanoparticles.

With respect to claim 14, Zaffaroni also teaches that the drug delivery device is a free flowing microcapsule (claimed dry flowable powder; see, e.g., 13:43-45).

Claims 5-6: Zaffaroni teaches that the nanoparticles are coated with essential fats useful as pharmacologically active agents (11:36-40).

4. Claim 8 is rejected under 35 U.S.C. 103(a) as being unpatentable over Zaffaroni and Fujiura in light of Barnhart.

Claim 8: Zaffaroni and Fujiura fail to teach that the coating process is repeated. However, Barnhart teaches that it is known in the art to repeat coating processes on pharmaceutical devices in order to obtain a coating with a desired thickness (8:5-7). Thus, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have repeated the steps of claim 1 in order to have obtained a coating with a desired thickness.

5. Claim 6 is rejected under 35 U.S.C. 103(a) as being unpatentable over Zaffaroni and Fujiura in light of Rubin (US 4,961,936).

Claim 6: Zaffaroni teaches that the nanoparticles are coated with essential fats useful as pharmacologically active agents, but fails to expressly teach that these essential fats are polyunsaturated fatty acids. However, the examiner takes official notice that polyunsaturated fatty acids, such as EPA and DHA, are well known in the art as pharmacologically active essential fats (see, e.g., Rubin, US 4,961,936 at 5:17-20).

6. Claims 2, 7, 9-13, 15-16 and 19-20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Zaffaroni and Fujiura in light of Lech.

Claims 2, 7 and 15-16: Zaffaroni and Fujiura fail to teach that the nanoparticles are silica. Lech, however, teaches a method of producing coated silica particles useful as drug release devices (2:45-55) and that silica is useful as a carrier material because it masks the bitter taste of the drug delivery device (2:45-55). Thus, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have used silica as the carrier particle in Zaffaroni in order to have masked the bitter taste of the coated drug delivery device.

Claims 9-13 and 19-20: Lech also teaches that sweeteners are added to the coated nanoparticles in order to improve their taste (3:60-4:15). While Lech does not explicitly teach sucrose as the sweetener, sucrose is well known in the art as a sweetener. Furthermore, with respect to the method used to deposit the sweetener as a coating liquid or as a liquid encapsulating material, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have utilized the method of Fujiura because it is the method which is already being used to coated the nanoparticles in the first step of the combined method of Zaffaroni and Fujiura.

With respect to the limitations “coating liquid” and “liquid encapsulating material,” according to applicant’s specification, on page 5, a sweetener qualifies under both of these categories.

With respect to the addition of a sweetener, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have incorporated a sweetener, such as sucrose, as taught by Lech, into the combined method of Zaffaroni and Fujiura in order to improve the taste of the drug delivery device.

7. Claim 17 is rejected under 35 U.S.C. 103(a) as being unpatentable over Zaffaroni, Fujiura and Lech as applied to claim 16 and further in view of Rubin (US 4,961,936).

Claim 17: Zaffaroni, Fujiura and Lech fail to teach what type of polyunsaturated fatty acid is used. However, both EPA and DHA are well known in the art as pharmacologically active essential fats (see, e.g., Rubin at 5:17-20). The selection of a known material based on its suitability for its intended use supported a prima facie obviousness determination in *Sinclair & Carroll Co. v. Interchemical Corp.*, 325 U.S. 327, 65 USPQ 297 (1945). Thus, it would have been obvious to one of ordinary skill in the art at

the time the invention was made to have selected EPA and DHA as the polyunsaturated fatty acids used in the combined method of Zaffaroni, Fujiura and Lech.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to ROBERT VETERE whose telephone number is (571)270-1864. The examiner can normally be reached on Mon-Fri 9-6.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Cleveland can be reached on 571-272-1418. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Robert Vetere/
Examiner, Art Unit 1792

/Michael Cleveland/
Supervisory Patent Examiner, Art Unit 1792